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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/760,151	01/15/2004	Farzan Filsoufi	MSSM-001	7208
24353	7590	08/23/2005	EXAMINER	
BOZICEVIC, FIELD & FRANCIS LLP 1900 UNIVERSITY AVENUE SUITE 200 EAST PALO ALTO, CA 94303			PREBILIC, PAUL B.	
			ART UNIT	PAPER NUMBER
			3738	

DATE MAILED: 08/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/760,151

Applicant(s)

FILSOUFI, FARZAN

Examiner

Paul B. Prebilic

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 July 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-42 is/are pending in the application.
- 4a) Of the above claim(s) 3, 4, 10, 11 and 20-42 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 5-9 and 12-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 8/31/04.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Election/Restrictions

Claims 3, 4, 10, 11, and 20-42 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions or species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on July 22, 2005.

Applicant's election with traverse of Group I, Species A and Species i in the reply filed on July 22, 2005 is acknowledged. The traversal is on the ground(s) that there is no serious burden to examine all the claimed inventions. This is not found persuasive because searching the method would require the review of at least two more subclasses. The consideration of the 23 additional claims and the additional prior art would be clearly burdensome. In addition, the species claimed clearly support other patents because they are mutually exclusive features and would require an entirely different structural analysis as it pertains to anticipation and obviousness.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 18 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The language "fixation means for attaching" is interpreted as a Section 112, sixth paragraph limitation. Since "fixation" and "attaching" are considered synonymous (American Heritage Dictionary, Second College Edition,

(1991)), it is unclear why both terms are used to describe the function. The Examiner suggests deleting one "fixation" in order to overcome this rejection since "means for attaching" is used in dependent claim 19.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 6 and 7 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Regarding claim 6, on line 2, the language "wherein a free margin of the prolapsing leaflet is positioned therein" attempts to claim the man-made structure in combination with the naturally occurring device. In order to overcome this rejection, the Examiner suggests changing "where" to ---such that--- and inserting ---adapted to be--- after "leaflet is."

Regarding claim 7, lines 1-2, the claim language positively claims the device in an implanted state and thus implicitly claims it in combination with the natural heart valve. The Examiner suggests replacing "which extends" with ---configured to extend--- in order to overcome this rejection.

Claim 14 is rejected under 35 U.S.C. 101 because the disclosed invention is inoperative and therefore lacks utility. Regarding claim 14, the Examiner queries how the claimed device could be operative since a 10 mm thick material would apparently clog the annulus. Since natural and artificial leaflet are on the order of 0.2 to 0.7 mm,

the Examiner asserts that the much higher range of leaflet thickness would be inoperative in a human or mammalian heart.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 5, 7-9, 12, and 16-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Streeter (US 2002/065554). Streeter discloses a structure to attach to a prolapsed leaflet and to extend over one or two leaflets; see Figures 2, 3, 5, 7, and 8-10 as well as the abstract, and paragraphs [0005] to [0011]. For this reason, the claim language is fully met.

Regarding claim 2, the structure of Streeter can be made with metal or wire such that it would be inherently be at least semi-rigid to the extent that this language can be give patentable weight; see paragraph [0025].

With regard to claim 18 and the "fixation means for attaching", this limitation meets the three-prong test per MPEP 2181 and thereby invokes 35 USC 112, 6th paragraph. Streeter's element (sutures or staples) is considered equivalent to Applicant's means for attaching (see claim 19) because it performs the same function in substantially the same way and produces the substantially the same result as the corresponding element of Applicant's specification; see MPEP 2183.

Claims 1, 5, 6, and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Gabbay (US 6,419,695). Gabbay anticipates the claim language where the structure of Gabbay is attachable to an intact valve, is capable of attachment via sutures to a prolapsing leaflet, and has a structure that is capable of coapting with an adjacent leaflet as claimed; see the figures and column 1, line 60 to column 2, line 29.

Regarding claim 6, the bifurcated configuration is that of the buttress that has two branches. The prolapsing leaflet could be attached between the two branches by sutures.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 13 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Streeter (US 2002/065554) alone. Streeter meets the claim language as explained in the Section 102 rejection, but fails to disclose the particular dimensions as claimed. However, when the only difference between the prior art and the claims is a recitation of some relative dimensions and the prior art device would not perform differently than the claimed device, the claimed device would have been considered *prima facie* obvious to an ordinary artisan. The following is an excerpt from MPEP 2144.04:

In Gardner v. TEC Systems, Inc., 725 F.2d 1338, 220 USPQ 777 (Fed. Cir. 1984), cert. denied, 469 U.S. 830, 225 USPQ 232 (1984), the Federal Circuit held that, where the only difference between the prior art and the

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claims was a recitation of relative dimensions of the claimed device and a device having the claimed relative dimensions would not perform differently than the prior art device, the claimed device was not patentably distinct from the prior art device.

Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gabbay (US 6,419,695) in view of Frey (US 5,607,469). Gabbay meets the claim language as explained in the Section 102 rejection above, but fails to disclose the thickness of the structure as claimed. However, Frey teaches that it was known to make similar rigid structure of heart valves in the 2 mm size range; see column 7, lines 52-64. Therefore it is the Examiners position that it would have been obvious to make the thickness of the Gabbay device in the range of about 2 mm so that it would be sufficiently rigid yet fit within the annulus of the heart.

Conclusion

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC 102 or 35 USC 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is respectfully requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is respectfully requested in response to this Office action if the application is not stored in image format (i.e. the IFW system) or published.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Paul B. Prebilic whose telephone number is (571) 272-4758. He can normally be reached on 6:30-5:00 M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, McDermott Corrine can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read "Paul Prebilic", with a stylized flourish at the end.

Paul Prebilic
Primary Examiner
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